Message

From: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Sent: 2/7/2017 5:57:01 PM
To: McNally, Robert [Mcnally.Robert@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]
Subject: RE: update on Oxitec

Yes, that is what I am wondering about. I guess it all depends on how fast FDA can get the approval from the new management for publishing the final of 236.

From: McNally, Robert
Sent: Tuesday, February 07, 2017 12:12 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: update on Oxitec

Quick point – if they get their revised amendment to FDA in late Feb, what if FDA puts out their final guidance before the amendment review action is completed and the work starts??

From: Milewski, Elizabeth
Sent: Tuesday, February 07, 2017 11:53 AM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: update on Oxitec

Hi, Bob. I spoke with Camilla Beach this morning. Keith Matthews was also on the line. He is now once again counsel for them.

Looks like my original agenda is what Camilla wants from the meeting. As you suggested, I should put time on the agenda for FDA's opportunity to inform the Thursday meeting as to where they are with their process. As we will be talking with FDA this afternoon, can we ask them whether they are comfortable with giving a brief update of where they are in their process at the Thursday meeting with Intrexon? (Camilla tells me Oxitec hopes to have their revised submission of the amendment to the EA request at FDA by the end of February). If FDA is willing to share, I will insert time for them on the agenda.

I will be trying to put together a best-guess time-line for the various transfer-of-jurisdiction options this afternoon and tomorrow. Don't know in advance if it will be something worth sharing with others – have to see if I can develop something acceptable within EPA. Given the amount of emphasis Camilla and Keith put on data requirements in this morning's phone call, I am guessing that Keith is thinking about suggesting the option of going for a section 3 directly without going through an EUP might be in play. So, it would seem important to include in our presentation information on section 3 and its requirements. This also brings up the question of how much, if any, of foreign-generated data can be used to support a section 3 – a question we likely need to resolve soon. However, we can punt on that at the Thursday meeting. Camilla tells me that all the data for the foreign trials has appeared in the published literature. She will send files to us.

I have a call in to Ben letting him know that Keith intends to attend the Thursday meeting as Intrexon legal counsel. They may also bring their FDA attorneys if they can work it out. So hopefully Chris K and Ben can attend. I hope to chat with Ben today about the other issues we discussed yesterday, e.g., what can happen at EPA in the time

between FDA's decision on the amended EA and FDA issuance of its final guidance 236. Assuming there actually is any time. With the FDA comment period on GFI 236 closing on February 21 and Oxitec hoping to submit their amended EA request by the end of February, it looks like FDA might have some options.

On a last note – Camilla tells me that although they would like to start their field trial prior to mid-May 2017, they intend to begin the trial whenever they get permission to proceed. So the window for starting testing would appear to extend from February through October. At least that is my guess from what was said in the conversation. Mosquito population numbers form a bell curve from February through November. They prefer earlier testing because it is easier technically to test when the population is lower; however they can test at any point in the curve including at the peak, it is just more complicated to do so when mosquito numbers are high.

I will phone in to the FDA/EPA call this afternoon.